Aaron Siri

From: Aaron Siri
Sent: Monday, November 13, 2017 12:28 PM
To: Gordon, Joshua (NIH/NIMH) [E]
Cc: dchristensen@cdc.gov; cso6@cdc.gov; dqc3@cdc.gov
Subject: RE: 1 selected item: 24814559 - PubMed
Attachments: Dr. Gordon Response.pdf; DTaP-Autism - 2011 IOM Report.pdf

Good afternoon Dr. Gordon,

I received the attached email from HHS which I assume is your official response to the simple request to provide at least one study which supports that DTaP and the other vaccines HHS recommends during the first year of life do not cause autism.

This response provides a link to the HHS webpage which claims "Vaccines Do Not Cause Autism" and lists a number of reviews/studies to support this assertion. Sadly, not a single one of these reviews/studies (which all related to either one vaccine, MMR, and/or one vaccine ingredient, thimerosal) provides a shred of support that the 29 doses of 9 different vaccines CDC recommends children receive by six months of age do not cause autism. Ironically, the very first study/review listed on this webpage is the 2011 IOM report, paid for by HHS, which looked at the most commonly claimed vaccine reactions, including that DTaP causes autism, and the IOM could not find a single study that supports the assertion that DTaP (injected at 2 months, 4 months, 6 months, etc.) does not cause autism. (See excerpt from the IOM report attached.) Your response therefore makes it clear you do not have a single study to share which supports that the vaccines given to children in the first year of life do not cause autism.

It is understandable that you thought the study you sent me below actually contained unexposed controls (unvaccinated children) given its misleading title. But now that you know the reality that there is no study supporting the claim that vaccines given during the first year of life do not contribute to the incidence of autism, are you going to take action to conduct an appropriate study that would either support or reject this claim?

I understand this is a difficult and controversial topic but I hope the National Institute of Mental Health and the IACC do not shy away from a scientific study because of fear of what it may show. There are a number of plausible reasons for how 29 doses of 9 different vaccines given during pregnancy, 1 day, 2 months, 4 months, and 6 months can cause autism, including immune activation, aluminum adjuvant being carried to the brain by macrophages, MCP-1 signaling, molecular mimicry, etc. Vaccines are intended to create a permanent change in the body's immune system often using adjuvants intended to generate a sustained and significant immune event which modern science is not even close to fully understanding; there is also a growing understanding of the connections between the immune and nervous systems. But no need to make this complicated since all you need to do is what is done for every drug pre-licensure. Compare the rates of neurological and immune disorders between an exposed group (vaccinated) and unexposed group (unvaccinated) – this study can even be done retrospectively to avoid supposed ethical concerns.

You are in the unfortunate position of defending vaccine safety because, unlike drugs, most pediatric vaccines currently on the market have been approved based on studies with inadequate follow-up periods of only a few days or weeks (and no saline placebo control). You however are in the fortunate position to remedy this deficiency. In that regard, I have attempted as best as I can to engage with you in a constructive manner on this topic, giving you many months since our meeting to provide the support you were adamant existed during our meeting (a study of vaccinated versus unvaccinated children). Absent a response in the coming days with such support or firm plans to openly conduct such a study, I am left with the conclusion that you (directly or by order of your superiors) don't care to know the real answer to the question of whether giving 29 doses of 9 different vaccines by six months of life contributes to the incidence of autism (and other neurological and immune issues).

Dr. Collins asked during our meeting to consider the implications if Mr. Kennedy was wrong about his concerns regarding vaccine safety. Given your station, I ask you the same question. What if you are wrong about the safety profile of the first year vaccination schedule? What if it is a major contributor to the rising incidence of various neurological and immune (including immune mediated neurological) disorders that have risen in tandem with the increase in HHS's recommended vaccine schedule. If you conduct the desperately needed vaccine safety science noted above the worst that will have happened is that you will have the science to prove what you now can only assume. However, if you don't conduct this study and it eventually turns out your belief (and this email chain makes clear it is a belief) regarding vaccine safety is incorrect, I hope you can live with knowing you could have avoided these harms (and provided the basis to finally begin the desperately needed science of identifying the children susceptible to serious vaccine injury) but chose instead to sit on your hands…

Very truly yours,
Aaron

From: Aaron Siri
Sent: Thursday, September 14, 2017 1:41 PM
To: 'Gordon, Joshua (NIH/NIMH) [E]' <joshua.gordon@nih.gov>
Cc: 'dchristensen@cdc.gov' <dchristensen@cdc.gov>; 'cso6@cdc.gov' <cso6@cdc.gov>; 'dqc3@cdc.gov' <dqc3@cdc.gov>
Subject: RE: 1 selected item: 24814559 - PubMed

Good afternoon Dr. Gordon,

Thank you for your response. The information I seek is nothing more than a simple reference to one study which supports HHS's claim that the vaccines it recommends children receive in the first year of life do not cause autism. I gather from our exchange below that you are not aware of any such study. Let me know if that is incorrect.

You are the Director of the Interagency Autism Coordinating Committee (IACC) which coordinates all efforts at HHS, including at the CDC, concerning autism. The IACC's members include the CDC itself, as well as the CDC's Chief Medical Officer & Associate Director for Science (Stuart K. Shapira, M.D., Ph.D.) and the CDC's Surveillance Team Lead, Developmental Disabilities Branch (Deborah Christensen, Ph.D.) Since you state below that the support I seek is best obtained from the CDC, I have cc'd the CDC members on your committee.

I am just trying to get a copy of a study supporting HHS's claim that the vaccines it recommends in the first year of life do not cause autism. I assume you have the best intentions and I would really like to drop this issue – but, as you can appreciate, I like to rely on data/science. I am just asking for a citation to a single study supporting HHS's claim that the vaccines it recommends children receive in the first year of life do not cause autism. I would think you too, as the Director of IACC and NIMH, would be interested in seeing such a study and its underlying data.

Also, can you kindly let me know one way or another if you are interested in meeting with the aluminum adjuvant experts whose letters and CVs were previously provided regarding the potential connection between aluminum adjuvants and autism. Again, I would think you would be interested in hearing them out. (Docs relevant to same reattached.)

Best regards,
Aaron

p.s. Btw, your response below reminds of me of what former House representative, Dr. Dave Weldon, wrote in 2007: "When I first tasked my staff with investigating federal vaccine safety research we got a lot of confused responses and blank stares from federal officials. The FDA told us to check in with the CDC, telling us that CDC did most of the vaccine

safety research. The CDC referred us over to the NIH. Then, the NIH referred us back to the CDC." Happy to send you his full statement.

From: Gordon, Joshua (NIH/NIMH) [E] [mailto:joshua.gordon@nih.gov]
Sent: Friday, September 1, 2017 3:40 PM
To: Aaron Siri <aaron@sirillp.com>
Subject: Re: 1 selected item: 24814559 - PubMed

Dear Aaron,

I appreciate you following up with me, and apologize for the delay in my response. I think the information you are seeking would be best obtained from the CDC.

Best,

Josh

Joshua A Gordon, MD, PhD
Director
National Institute of Mental Health

From: Aaron Siri <aaron@sirillp.com>
Date: Monday, August 14, 2017 at 4:48 PM
To: "M. Joshua Gordon" <joshua.gordon@nih.gov>
Subject: RE: 1 selected item: 24814559 - PubMed

Dr. Gordon,

I hope all is well.

I have not received a response to the emails below of July 10 and July 24.

The July 10 email was in response to a review you provided indicating it compared vaccinated and unvaccinated children (but which actually compares vaccinated children with vaccinated children who, at most, were missing MMR). As discussed at our meeting, I would like to see a study which supports the claim that the nearly two dozen doses of vaccines given in the first year of life (which would not include MMR and thimerosal) do not cause autism. I still await receipt of a study which supports same. Are you aware of any such study?

The July 24 email elaborated on my prior email and also sought to facilitate a meeting between with various experts in the field of aluminum adjuvant that do believe there is a connection between aluminum adjuvant in vaccines and autism. Are you willing to have this meeting?

Best regards,
Aaron

From: Aaron Siri
Sent: Monday, July 24, 2017 6:18 PM

To: 'Gordon, Joshua (NIH/NIMH) [E]' <joshua.gordon@nih.gov>
Subject: RE: 1 selected item: 24814559 - PubMed

Good evening Joshua,

As promised in my email below, I am following up regarding the research that has been conducted regarding aluminum adjuvants and neuro/psychiatric disorders, and to facilitate a meeting with you and the scientists conducting this research.

In recent years researchers have discovered that injected aluminum adjuvant travels into the brain, where it causes long term chronic inflammation, damage to neurons and behavioral abnormalities. These adverse effects occur at dosages (mcg/Kg body weight) even lower than dosages received by infants according to the CDC vaccine schedule.

Additionally, it is now well established that autism and other neuro/psychiatric disorders are caused by early life inflammation (i.e. elevated cytokines) in the brain. I have seen your published papers on immune activation and brain development so I presume you are aware of the immune activation findings. Aluminum adjuvant can cause chronic brain inflammation, and this establishes a biologically-plausible and empirically-supported mechanism for how vaccines may cause autism and other neurological disorders. None of the vaccine-autism studies to date tell us anything about the safety of aluminum adjuvants. There are no epidemiological studies showing that aluminum adjuvants do not produce these effects in humans.

Attached is a detailed explanation of the proposed mechanism for how aluminum adjuvants may cause autism. The mechanism suggests that aluminum adjuvant may cause other brain and neurodevelopmental disorders as well. Attached are also supporting letters from experts in the fields of aluminum toxicity. (Finally, I have also attached a more detailed analysis of Taylor 2014.)

I invite you to consider the arguments in the attached document and respond with your observations. I also invite you to share the document with colleagues, particularly if they may have insightful comments or rebuttals.

I also hope to facilitate a meeting with you and a number of the experts studying aluminum adjuvant toxicity, letters from a number of which are attached to this email. Assuming you are open to having this discussion, kindly have your office provide suggested dates/times for such a meeting.

Best regards,
Aaron

From: Aaron Siri
Sent: Monday, July 10, 2017 4:16 PM
To: 'Gordon, Joshua (NIH/NIMH) [E]' <joshua.gordon@nih.gov>
Subject: RE: 1 selected item: 24814559 - PubMed

Good afternoon Joshua,

Thank you for sending me the below abstract/review article and it was great meeting at NIH. Really appreciate the opportunity to dialogue on the issue of vaccines and autism.

The abstract/review article you sent me below highlights the concern raised that there has never been a study assessing the relative risk of autism between vaccinated and unvaccinated child. To be sure, this review (and its

abstract) leave the impression that the studies it relies upon compare "unvaccinated" children (no vaccines) with vaccinated children. Unfortunately, this is misleading since all 10 of the underlying studies relied upon for this review compared highly vaccinated children with highly vaccinated children. The only difference typically between the study and control groups was a single MMR vaccine or thimerosal vs. non-thimerosal vaccines. (I would be happy to provide you with a breakdown of each of the 10 studies reflecting same.) Meaning, what this review considers "unvaccinated" are vaccinated children typically only missing the MMR vaccine. Assuming the control children in these studies followed the current CDC recommended vaccination schedule, they would each have received 21 vaccine injections during the first 12 months of life excluding the MMR vaccine. Hence, these studies tell us virtually nothing about the relationship of vaccines to autism because they are not comparing vaccinated and unvaccinated children.

For example, the IOM stated in 2011 that there isn't a single study that supports the assertion that DTaP (injected at 2 months, 4 months, 6 months, etc.) does not cause autism, concluding that "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and autism." Attached is an excerpt of the discussion regarding autism and DTaP from the 2011 IOM report. (I am not aware of a single study regarding DTaP and autism that has been done since 2011.) As another example, the only study regarding Hepatitis B vaccine and autism I have located found a three-fold increase in the odds of an autism diagnosis for neonates that received the hepatitis B vaccine at birth compared that those that did not. (Gallagher CM, Goodman MS. 2010. Hepatitis B vaccination of male neonates and autism diagnosis, NHIS 1997-2002. J Toxicol Environ Health A. 73(24):1665-77.) There is simply no studies for the numerous other vaccines given to children during the first year of life with regard to their relationship with autism (except for the Mawson study which showed vaccination had an over 4 fold increase in autism risk but that study has some serious limitations).

As we discussed at the meeting, I really am open to seeing the evidence that the vaccination schedule, and in particular the cumulative impact of the 31 vaccine doses the CDC recommends a child receive in the first year of life, are not casually related to autism. I would gladly share that support with the community concerned with this issue with my personal endorsement. On the other hand, if that proof doesn't exist, that does not mean that vaccines cause autism. It just means that we need to really do the science necessary to rule out that possibility. (Seeking to assess the health outcomes of those receiving vaccines and those not receiving vaccines really is asking for nothing more than how all drugs are safety tested prior to licensure.)

I respected what appeared to be your thoughtful rather than reflexive reaction to the spirited discussion at NIH. Conducting a true study of the health outcomes between actually unvaccinated and vaccinated children (at least an initial quick and easy retrospective study) that shows no connection with autism should be something that everyone should want. If it shows no connection, it will likely provide the greatest relief to the portion of the autism community that thinks there may be a connection. Parents who think that it was their actions, in vaccinating their children, that lead to their child's condition would feel freed from that guilt by knowing it wasn't the vaccines.

I look forward to your response and being persuaded that the science on the question of whether vaccines cause autism really is settled.

Thanks again in advance for your time and thoughtful consideration of this issue.

Best regards,
Aaron

p.s. I have had a number of discussions with various aluminum adjuvant experts around the globe who believe there is a connection between the aluminum adjuvants in vaccines given in large quantities during the first six months of life and autism; I hope to soon send you a write-up regarding same for your consideration.

From: Gordon, Joshua (NIH/NIMH) [E] [mailto:joshua.gordon@nih.gov]
Sent: Wednesday, May 31, 2017 4:03 PM
To: Aaron Siri <aaron@sirillp.com>
Subject: Fwd: 1 selected item: 24814559 - PubMed

Joshua A Gordon, MD, PhD
Director
National Institute of Mental Health

Begin forwarded message:

From: Sent by NCBI <nobody@ncbi.nlm.nih.gov>
Date: May 31, 2017 at 4:00:01 PM EDT
To: <Joshua.gordon@nih.gov>
Subject: 1 selected item: 24814559 - PubMed

This message contains search results from the National Center for Biotechnology Information (NCBI) at the U.S. National Library of Medicine (NLM). Do not reply directly to this message

Sent on: Wed May 31 15:58:39 2017

1 selected item: 24814559

PubMed Results

Item 1 of 1 (Display the citation in PubMed)

1. Vaccine. 2014 Jun 17;32(29):3623-9. doi: 10.1016/j.vaccine.2014.04.085. Epub 2014 May 9.

Vaccines are not associated with autism: an evidence-based meta-analysis of case-control and cohort studies.

Taylor LE[1], Swerdfeger AL[1], Eslick GD[2].

Author information:

1

The Whiteley-Martin Research Centre, Discipline of Surgery, The University of Sydney, Nepean Hospital, Level 3, Clinical Building, PO Box 63, Penrith 2751, NSW, Australia.

2

The Whiteley-Martin Research Centre, Discipline of Surgery, The University of Sydney, Nepean Hospital, Level 3, Clinical Building, PO Box 63, Penrith 2751, NSW, Australia. Electronic address: guy.eslick@sydney.edu.au.

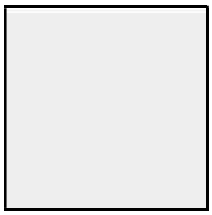
Comment in

- Autism and vaccination: The value of the evidence base of a recent meta-analysis. [Vaccine. 2015]
- Answers regarding the link between vaccines and the development of autism: A question of appropriate study design, ethics, and bias. [Vaccine. 2015]

Abstract

There has been enormous debate regarding the possibility of a link between childhood vaccinations and the subsequent development of autism. This has in recent times become a major public health issue with vaccine preventable diseases increasing in the community due to the fear of a 'link' between vaccinations and autism. We performed a meta-analysis to summarise available evidence from case-control and cohort studies on this topic (MEDLINE, PubMed, EMBASE, Google Scholar up to April, 2014). Eligible studies assessed the relationship between vaccine administration and the subsequent development of autism or autism spectrum disorders (ASD). Two reviewers extracted data on study characteristics, methods, and outcomes. Disagreement was resolved by consensus with another author. Five cohort studies involving 1,256,407 children, and five case-control studies involving 9,920 children were included in this analysis. The cohort data revealed no relationship between vaccination and autism (OR: 0.99; 95% CI: 0.92 to 1.06) or ASD (OR: 0.91; 95% CI: 0.68 to 1.20), nor was there a relationship between autism and MMR (OR: 0.84; 95% CI: 0.70 to 1.01), or thimerosal (OR: 1.00; 95% CI: 0.77 to 1.31), or mercury (Hg) (OR: 1.00; 95% CI: 0.93 to 1.07). Similarly the case-control data found no evidence for increased risk of developing autism or ASD following MMR, Hg, or thimerosal exposure when grouped by condition (OR: 0.90, 95% CI: 0.83 to 0.98; p=0.02) or grouped by exposure type (OR: 0.85, 95% CI: 0.76 to 0.95; p=0.01). Findings of this meta-analysis suggest that vaccinations are not associated with the development of autism or autism spectrum disorder. Furthermore, the components of the vaccines (thimerosal or mercury) or multiple vaccines (MMR) are not associated with the development of autism or autism spectrum disorder.

PMID: 24814559 [Indexed for MEDLINE]



Aaron Siri

From: CDCExecSec (CDC) <CDCExecSec@cdc.gov>
Sent: Wednesday, October 25, 2017 8:19 AM
To: Aaron Siri
Subject: Vaccine Inquiry

Dear Mr. Siri:

Thank you for your inquiry. The Centers for Disease Control and Prevention (CDC) information on vaccines and autism can be found here, www.cdc.gov/vaccinesafety/concerns/autism.html.

Please send any future correspondence to CDCExecSec@cdc.gov.

Sincerely,

Sandra Cashman, MS
Executive Secretary
Office of the Chief of Staff, CDC

Adverse Effects of Vaccines

Evidence and Causality

Committee to Review Adverse Effects of Vaccines

Board on Population Health and Public Health Practice

Kathleen Stratton, Andrew Ford, Erin Rusch, and Ellen Wright Clayton,
Editors

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

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Weight of Epidemiologic Evidence

The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and ataxia.

Mechanistic Evidence

The committee identified one publication reporting the development of ataxia after the administration of DTaP vaccine. Kubota and Takahashi (2008) did not provide evidence of causality beyond a temporal relationship of 2 days between vaccine administration and development of cerebellar symptoms leading to a diagnosis of acute cerebellar ataxia. The publication did not contribute to the weight of mechanistic evidence.

Weight of Mechanistic Evidence

The committee assesses the mechanistic evidence regarding an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and ataxia as lacking.

Causality Conclusion

Conclusion 10.5: The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and ataxia.

AUTISM

Epidemiologic Evidence

The committee reviewed one study to evaluate the risk of autism after the administration of DTaP vaccine. This one study (Geier and Geier, 2004) was not considered in the weight of epidemiologic evidence because it provided data from a passive surveillance system and lacked an unvaccinated comparison population.

Weight of Epidemiologic Evidence

The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism.

Mechanistic Evidence

The committee did not identify literature reporting clinical, diagnostic, or experimental evidence of autism after the administration of vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens alone or in combination.

Weight of Mechanistic Evidence

The committee assesses the mechanistic evidence regarding an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism as lacking.

Causality Conclusion

Conclusion 10.6: The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism.

ACUTE DISSEMINATED ENCEPHALOMYELITIS

Epidemiologic Evidence

No studies were identified in the literature for the committee to evaluate the risk of acute disseminated encephalomyelitis (ADEM) after the administration of vaccines containing diphtheria toxoid, tetanus toxoid, or acellular pertussis antigens alone or in combination.

Weight of Epidemiologic Evidence

The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccines and ADEM.

Mechanistic Evidence

The committee identified five publications of ADEM developing after the administration of vaccines containing diphtheria toxoid and tetanus toxoid antigens alone or in combination. Four publications did not provide evidence beyond temporality, one of which was deemed too short based on the possible mechanisms involved (Abdul-Ghaffar and Achar, 1994; Bolukbasi and Ozmenoglu, 1999; Hamidon and Raymond, 2003; Rogalewski et al., 2007). In addition, Rogalewski et al. (2007) reported the administration of vaccines against hepatitis B, hepatitis A, and poliovirus in